UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: February 22, 2011

SUBJECT: Imidacloprid. Study Review of Passive Dosimetry and Inhalation Monitoring Aspects of "GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals".

PC Code: 129099
Decision No.:
Petition No.:
Risk Assessment Type:
TXR No.:
MRID No.: 47054701

DP Barcode: 386913
Registration No.:
Regulatory Action:
Case No.:
CAS No.: 138261-41-3, 105827-78-9
40 CFR:

FROM: Seyed Tadayon, Chemist
Risk assessment Branch V
Health Effects Division (7509P)

Through: Jack Arthur, Chief
Risk assessment Branch V
Health Effects Division (7509P)

To: Dana Vogel, Chief
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Health Effects Division (7509P)

Attached is a review of the study of "Determination of Passive Dosimetry and Inhalation Monitoring Aspects of "GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed treatment of Cereals" submitted by Bayer CropScience. The study review was conducted by Versar, Inc. A secondary review was conducted by HED.

FEB 25 REC'D, 2011

The purpose of the study was to determine the dermal and inhalation exposure of handlers during the treatment and planting of cereal grain seeds with the insecticide imidacloprid. . Twelve trials were conducted examining on-farm treater/planters and four were conducted examining exposure to commercial treaters. The study was conducted at fourteen field sites throughout South Dakota, North Dakota, Minnesota, and Montana.

A solution concentrate formulation of 41.67 % imidacloprid (GAUCHO 480 SC) was used to treat the seeds at a target rate of 0.01 lb ai/100 lbs seed. Workers performed their normal activities in treating (commercial) facilities and or treating and planting (on-farm) cereal grain seeds. The seed type treated was listed as wheat seed for some of the replicates, but was unspecified for other replicates.

In the commercial facility the application rate was to 0.01 lb ai/100 lbs seed (0.32 fl oz GAUCHO 480 SC per 100 lbs seed). The monitoring duration for the commercial mixing/loading and application procedure ranged from 4.3 to 10.6 hours. The on farm handlers treater/planter subjects (treater/planter) handled 1.28 to 3.16 lbs ai while treating 9,900 to 28,800 lbs of seed.

Each handler wore long sleeve shirt and pants, chemical resistant gloves, shoes and socks. Fourteen of the 16 workers wore a baseball cap.

Dermal exposure was estimated by measuring residues on or in inner whole body dosimeters, face/neck wipes, and hand washes. Potential inhalation exposure was assessed by measuring personal air concentrations using sampling pumps attached to an OVS tube sample collector. The pumps operated at a flow rate of 2.0 L/min.

Total dermal exposures for commercial seed treaters and on-farm treater/planters were normalized by lb ai handled. Total dermal exposure was determined by summing the estimated inner dosimeter exposure, hand exposure (hand wash residues after exposure), and face/neck exposure (face/neck wipes). Total dermal exposure ranged from 26.4 to 137 µg/lb ai, with an average of 72.0 ± 49.0 µg/lb ai for commercial treaters and from 6.61 to 231 µg/lb ai with an average of 65.4 ± 68.1 µg/lb ai for on-farm treater/planters.

Total inhalation exposure ranged from 0.07 to 31.3 µg/lb ai with an average of 3.52 ± 8.78 µg/lb ai for on-farm treater/planters and from 0.107 to 1.55 µg/lb ai with an average of 0.548 ± 0.673 µg/lb ai for commercial treaters. NAFTA recommended inhalation rate of 0.0167 m^3/min (light activities) was used in the calculation.

The summary of total dermal and inhalation exposure is presented in the table below:

Summary Total Dermal and Inhalation Exposure (µg/lb ai)	
Dermal Exposure (µg/lb ai) for On-farm Treater/Planters	
Overall Average	65.4
Overall Standard Deviation	68.1
Overall Geo mean	39.3
CV (%)	104
Min	6.61
Max	231

Dermal Exposure (µg/lb ai) for Commercial Treaters	
Overall Average	72.0
Overall Standard Deviation	49.0
Overall Geo mean	59.7
CV (%)	68.1
Min	26.4
Max	137
Inhalation Exposure for Commercial Treaters	
Overall Average	0.548
Overall Standard Deviation	0.673
Overall Geo mean	0.325
CV (%)	123
Min	0.107
Max	1.55
Inhalation Exposure for On-farm Treater/Planters	
Overall Average	3.52
Overall Standard Deviation	8.78
Overall Geo mean	0.887
CV (%)	250
Min	0.070
Max	31.3

Conclusion

The objective of this study was to determine the dermal and inhalation exposure of workers performing commercial and on-farm seed treatment to cereals. The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100(dermal exposure) and 875.1300(inhalation exposure). Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.

EPA Reviewer: _____ **Signature:** _____
Health Effects Division (7509C) **Date:** _____
Template version 02/06

DATA EVALUATION RECORD

STUDY TYPE: Agricultural Mixer/Loader, Applicator and Planter, Worker Exposure Study Employing Passive Dosimetry Techniques

PC CODE: 129099 or 129059

TEST MATERIAL: The test material was GAUCHO 480 SC (also called GAUCHO 480 F) is a solution concentrate or flowable formulation containing 41.67% of the active ingredient (ai) imidacloprid.

SYNONYMS:
Trade name: GAUCHO 480 SC or GAUCHO 480 F
Chemical name (CAS): 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitrol-2-imidazolidinimine
Chemical name (IUPAC): 1-(6-Chloro-3-pyridinyl)methyl-N-nitroimidazolidin-2-ylideneamine

CITATION:

Study Author:	M.E. Krolski
Title:	GAUCHO 480 SC – Worker Exposure During On-farm and Commercial Seed Treatment of Cereals
Report Date:	November 20, 2006
Performing Laboratory:	Bayer CropScience Environmental Research Bayer Research Park 17745 South Metcalf Ave. Stilwell, KS 66085-9104
Identifying Codes:	Bayer CropScience Study/PSI/Report Number: RANTY012

SPONSOR: Bayer CropScience
2 T. W. Alexander Drive
Research Triangle Park, NC 27709

EXECUTIVE SUMMARY:

This study was designed to examine dermal and inhalation exposure to 16 handlers during the treatment and planting of cereal grain seeds with the insecticide imidacloprid. Twelve trials were conducted examining on-farm treater/planters and four were conducted examining exposure to commercial treaters. GAUCHO 480 SC (a solution concentrate formulation of imidacloprid) was used to treat the seeds at a target rate of 0.01 lb ai/100 lbs seed (0.32 fl oz formulated product/100 lbs seed). Treating equipment included the Gustafson Farmer Applied Seed Treater (FAST), the Gustafson Total Slurry Treater (TST), the Gustafson CS 1700, and shop-made equipment. Each worker performed their normal activities in treating (commercial) or treating and planting (on-farm) cereal grain seeds. The seed type treated was listed as wheat seed for some of the replicates, but was unspecified for other replicates.

The study was conducted at fourteen field sites throughout South Dakota, North Dakota, Minnesota, and Montana. The field sites included eleven grower operations and three commercial seed treating facilities representing a range of personnel, treating and planting equipment. Sixteen individual male workers were monitored for exposure. Twelve on-farm treater/planters and four commercial seed treaters were monitored. Mixing of the test product was accomplished by open pouring of the GAUCHO 480 SC into either a container of RAXIL MD Extra, a mixing container, or directly into the reservoir of the seed treating equipment. As per label directions, the test substance, GAUCHO 480 SC, was used concurrently with a fungicide, RAXIL MD Extra, to treat the seeds. All the seed treatment equipment, with the exception of the Gustafson CS 1700, delivered the seed treatment mixture to a grain auger, where it was mixed with the seed by the action of the auger. The Gustafson CS 1700 treater included a mixing chamber where seed treatment mixture and seed were mixed. The treated seed was transferred to either a storage hopper or planter. The equipment was calibrated for use of RAXIL at approximately 5 fl oz/100 lbs cereal seed. The observed mix ratio of approximately 21 fl oz test substance per 2.5 gallons of RAXIL MD yielded a treating rate equivalent to 0.01 lb ai/100 lbs seed (0.32 fl oz GAUCHO 480 SC per 100 lbs seed).

The treater/planter subjects (on-farm handlers) handled 1.28 to 3.16 lbs ai while treating 9,900 to 28,800 lbs of seed. After treating the seed they planted 16 to 189 acres. The monitoring duration for the treater/planter replicates' mixing/loading/application and planting activities ranged from 3.8 to 11.2 hours. The commercial seed treaters handled 5.0 to 6.4 lbs ai while treating 50,100 to 59,380 lbs of seed. The monitoring duration for the commercial mixing/loading and application procedure ranged from 4.3 to 10.6 hours.

Each handler wore the label required personal protective equipment (PPE) consisting of long sleeve shirt and pants, chemical resistant gloves, shoes and socks. One of the workers also elected to wear a dust mask at various times during the work period. Fourteen of the 16 workers wore a baseball cap. One worker wore a visor and another did not wear any head protection.

The potential for dermal exposure was assessed by measuring residues from the inner dosimeters (100% cotton whole body dosimeters (WBD)), hand washes, and face/neck wipes. Potential inhalation exposure was assessed by measuring personal air concentrations using sampling pumps attached to an OVS tube sample collector. The sample collector consisted of a glass fiber filter at the air inlet, followed by two sections of XAD-2 housed in a 13 mm diameter glass tube. The OVS tube was held in a plastic tube holder and clipped to the worker's outer shirt collar with the intake facing downward. The pumps operated at a flow rate of 2.0 L/min.

Field fortification samples were collected during four of the eight monitoring periods for each matrix. Versar corrected the field sample residue when the fortification levels were <100%. The average recovery from the fortification level closest to the actual field residue level was used to correct the field residues. The limit of quantitation (LOQ) for the analytical method was 1 µg/sample for all dermal samples and 0.025 µg/sample for the OVS tubes. The limit of detection (LOD) was 0.04, 0.15, 0.05, and 0.004 µg/sample for the inner dosimeters, hand washes, face/neck wipes, and OVS tubes, respectively. For residues reported as <LOQ or <LOD, a value of ½ the LOQ or ½ the LOD respectively was used for calculation purposes.

Versar estimated dermal and inhalation exposure values as µg/lb ai handled using the corrected residues. The results have been grouped into 2 exposure categories, commercial seed treaters (n=4) and on-farm treater/planters (n=12).

Dermal Results

Residues were above the detection limit in the majority of samples. Dermal exposure was estimated by measuring inner WBD, face/neck wipe and hand wash residues. Total dermal exposures for commercial seed treaters and on-farm treater/planters were normalized by lb ai handled. Total dermal exposure was determined by summing the estimated inner dosimeter exposure, hand exposure (hand wash residues after exposure), and face/neck exposure (face/neck wipes). Total dermal exposure ranged from 26.4 to 137 µg/lb ai, with an average of 72.0 ± 49.0 µg/lb ai for commercial treaters and from 6.61 to 231 µg/lb ai with an average of 65.4 ± 68.1 µg/lb ai for on-farm treater/planters. The body part contributing the most to dermal exposure was the hands for both the commercial and on-farm replicates (average of 72.7% and 58.4% of the total, respectively).

Inhalation Results

Versar calculated inhalation exposures for the on-farm treater/planters and commercial treaters using the NAFTA recommended inhalation rate of 0.0167 m^3/min (light activities). Imidacloprid residues were not detected in the back section of the OVS tubes. Total inhalation exposure ranged from 0.07 to 31.3 µg/lb ai with an average of 3.52 ± 8.78 µg/lb ai for on-farm treater/planters and from 0.107 to 1.55 µg/lb ai with an average of 0.548 ± 0.673 µg/lb ai for commercial treaters.

Registrant Results

Versar and the Registrant used the same basic method to calculate total dermal exposure and inhalation exposure. Differences in both the dermal and inhalation exposure estimates are partially a result of field fortification correction methods used. The field fortification recoveries applied by Versar were not corrected for background residues, whereas the field fortification recoveries applied by the Registrant were corrected for background residues. Also, the Registrant corrected residues less than the LOQ, whereas Versar did not and the Registrant corrected residues for field fortification recoveries >100% using field fortification samples from the same sample set as when the field sample was analyzed, while Versar applied the average recoveries (<100%) from the fortification level most representative of the actual field residue level to correct the field residues.

Issues of concern when reviewing this study are:

- **Application Rate**
  The handlers treated the cereal seed with the label specified maximum rate for wireworm treatment (0.32 fl oz product/100 lbs seed). A current (dated 2009) label for GAUCHO 480 Flowable (EPA Reg. No. 264-957) specifies a rate that is 10 times greater for wheat seed treatment against other insects (3.0 fl oz product/100 lbs seed). It is possible, however, that at the time of the study the use rate of 0.32 fl oz product/a00 lbs seed was the maximum application rate.

- **Field Fortification**
  The fortification levels were not representative of the residue levels determined in the field samples for face/neck wipes. Face/neck wipe sample residues were primarily below the lowest fortification level.

  Also, field fortification samples were prepared at only 4 of the 16 trials.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C).

ETHICS REVIEW: Each trial consisted of a single worker performing their normal work activities, either as a treater/planter or a commercial treater. Prior to any work activities, signed consent forms were obtained from the workers. Both the protocol and the consent forms were approved by the Western Institutional Review Board (WIRB). his study was reviewed and approved by the Independent Investigational Review Board, Inc. (IIRB), an institutional review board, prior to study initiation. The IIRB also provided continued oversight of the field phase of the study in accordance with US EPA 40 CFR Part 26 Protection of Human Subjects. The study protocol was also submitted to the EPA prior to study initiation and determined by EPA to be an observational study not involving intentional exposure to a human subject as defined in 40 CRF §26.202(a). In compliance with Subpart M – Requirements for Submission of Information on the Ethical Conduct of Completed Human Research, Attachment B of the report contains an Ethics Information Requirements and Response Checklist which documents ethical conduct of this study.

GUIDELINE OR PROTOCOL FOLLOWED: The study was reviewed using OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group A: 875.1100 (dermal exposure), and 875.1300 (inhalation exposure).

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material:

Active ingredient:	Imidacloprid
Formulation:	GAUCHO 480 SC (also called GAUCHO 480 F). A solution concentrate or flowable formulation containing 40.7% of the active ingredient (ai) imidacloprid. The actual concentration was analyzed as 41.67% active ingredient (May 3, 2008; expiration date).
Purity technical:	96.9% (November 20, 2007; expiration date).
Batch # technical:	0126200521
Batch # formulation:	509403M
CAS #(s):	105827-41-3 or 138261-41-3
Other Relevant Information:	EPA Reg. No. 264-962 or EPA Reg. No. 264-957

2. Relevance of Test Material to Proposed Formulation(s):

The test product was GAUCHO 480 SC containing a nominal 40.7% of the active ingredient, imidacloprid. A reported deviation stated that the product received at the field sites was labelled GAUCHO 480 F and that the formulation was the same as GAUCHO 480 SC. A product label was not provided with the study, however, Versar obtained a copy of the label for GAUCHO 480 flowable from EPA's PPLS (EPA Reg. No. 264-957). The percent active ingredient, formulation and uses were the same.

3 Packaging:

The test material was packaged in quart sized (32 oz) plastic containers with screw type lids containing 480 g ai/L (4.01 lbs ai/gallon).

B. STUDY DESIGN:

The study was conducted according to protocol No. RANTY012 dated February 17, 2006. There study provided information on four protocol amendments and ten protocol deviations. The protocol deviations included issues such as not storing the test substance between 41 and 104°F at one of the field sites, not calibrating air sampling pumps prior to use, not checking air sampling pump operation at hourly intervals, not reporting cloud cover, not providing seed treating equipment description and test site diagram for Replicate #7, and not returning all of the test substance containers to Bayer CropScience. None of the protocol deviations negatively impacted the results of the study.

1. Number and type of handlers and sites:

The study was conducted at fourteen field sites throughout South Dakota, North Dakota, Minnesota, and Montana. The field sites included eleven grower operations and three commercial seed treating facilities representing a range of personnel, treating and planting equipment. Sixteen individual male workers were monitored for exposure. Twelve were on-farm treater/planters and four were commercial seed treaters. Ten of the twelve participating on-farm treater/planter replicates were owner-operators. Two of the treater/planter replicates and the four commercial treater replicates were employees of the participating facilities.

2. Meteorology:

Air temperature, relative humidity, rainfall, and wind speed and direction were monitored on each day of exposure monitoring. Cloud cover was not recorded. A rainfall event occurred on April 18, 2006 that caused the early termination of the planting activities for Replicate #5. A summary of the weather conditions at each site for the monitoring duration is shown in Table 1.

Table 1. Summary of Weather Conditions During the Monitoring Period

Handler ID	Type	Location	Monitoring Date	Wind Speed Range (mph)	Wind Direction	Air Temperature Range (°C)	Relative Humidity Range (%)	Rainfall (inches)
1	CT	Groton, SD	4/24/06	9.55-15.5	N	0.73-4.16	65.3-96.8	0.12
2	CT	Arvilla, ND	4/27/06	2.91-15.8	S	8.23-21.7	23.3-57.8	0
3	T/P	Richland, MT	5/15/06	2.08-5.4	SW	12.5-22.1	26.8-62.8	0
4	T/P	Berthold, ND	5/16/06	1.66-11.6	N	10.2-23.6	22.3-73.3	0
5	T/P	Bath, SD	4/18/06	12.9-18.3	SE	10.6-11.8	78.8-86.8	0
6	T/P	Grandin, ND	4/26/06	5.81-15.8	SW	14.9-21.0	15.8-30.8	0
7	T/P	Buxton, ND	4/26/06	5.81-15.8	SW	14.9-21.0	15.8-30.8	0
8	T/P	Aneta, ND	4/27/06	2.91-24.9	S	8.23-22.5	23.3-85.8	0.254
9	T/P	E. Grand Forks, MN	4/28/06	4.57-16.6	SE	8.63-16.8	54.3-97.3	0.01
10	T/P	Richland, MT	5/15/06	2.08-5.4	SW	12.5-22.1	26.8-62.8	0
11	T/P	Williston, ND	5/16/06	2.49-12.9	W	12.9-25.2	38.4-44.2	0
12	CT	Berthold, ND	5/16/06	2.49-12.9	W	13.7-21.3	39.8-44.2	0
13	T/P	Berthold, ND	5/16/06	2.91-8.3	W	18.7-26.0	38.6-44.8	0

Table 1. Summary of Weather Conditions During the Monitoring Period

Handler ID	Type	Location	Monitoring Date	Wind Speed Range (mph)	Wind Direction	Air Temperature Range (°C)	Relative Humidity Range (%)	Rainfall (inches)
14	CT	Berthold, ND	5/17/06	1.66-11.6	N	10.2-24.0	22.3-73.3	0
15	T/P	Des Lacs, ND	5/17/06	1.66-11.6	N	15.2-24.0	22.3-71.8	0
16	T/P	Donnybrook, ND	5/17/06	2.08-11.6	N	17.9-24.0	22.3-35.3	0

TP = Treater/planter; CT = Commercial treater

3. Replicates:

Sixteen handlers were monitored. Each trial consisted of a single handler performing their normal work activities, either as a treater/planter or as a commercial treater. The handlers performed their typical seed treating and planting of treated seed at grower facilities, and seed treating activities at commercial seed dealers. All of the handlers utilized open pouring of the test product while performing their mixing and loading duties. Twelve of the replicates were on-farm grower/planters and four were commercial treaters. Details of each individual handler are described in Table 2.

The handlers ranged in age from 28 to 60 years with 2 to 37 years of experience. The treater/planter subjects handled 1.28 to 3.16 lbs ai while treating 9,900 to 28,800 lbs of seed. After treating the seed the on-farm treaters also planted 16 to 189 acres. The monitoring duration for the growers' mixing/loading/treating and planting activities ranged from 3.8 to 11.2 hours. The commercial seed treaters handled 5.0 to 6.4 lbs ai while treating 50,100 to 59,380 lbs of seed and were monitored for durations ranging from 4.3 to 10.6 hours.

Table 2. Replicate Summary

Mixer/Loaders/Applicator																
Subject ID	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Type	CT	CT	T/P	T/P	T/P	T/P	T/P	T/P	T/P	T/P	T/P	CT	T/P	CT	T/P	T/P
Equipment Type																
Mixing/Loading Type	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour	Open pour
Treater Type	FT	Shop-made	TST	TST	TST	TST	TST	TST	TST	TST	TST	CS 1700	TST	CS 1700	TST	FT
Mixing/Loading, Treatment and Planting Parameters																
Crop Treated	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds	Cereal Seeds
Lb ai Mixed/Loaded/Applied	6.1	6.4	1.3	2.0	1.3	1.3	2.8	3.2	2.0	1.3	2.0	5.3	1.6	5.0	1.3	2.6
Lbs seeds treated	50,100	59,380	12,780	18,000	9,900	13,800	19,500	17,220	16,200	13,800	16,965	50,220	16,800	57,000	14,100	28,800
Bushels treated	835	990	213	300	165	230	325	287	270	230	283	837	280	950	235	480
Acres Planted	NA	NA	142	160	16	115	160	149	152	102	145	NA	98	NA	139	186
Total Monitoring Time (min)	390	472	574	591	227	526	503	672	672	598	488	256	390	635	605	572
Total Monitoring Time (hours)	6.5	7.9	9.6	9.9	3.8	8.8	8.4	11.2	11.2	10.0	8.1	4.3	6.5	10.6	10.1	9.5
Attire and PPE Worn																
Chemical- Resistant Gloves[a]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Single Layer Long Pants and Long Shirt	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Shoes/Socks[b]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hat[c]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes
Respirator	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Protective Eyewear[d]	Eye	Safety	Sun	None	Eye	Sun	Eye	Sun	Eye	Eye	None	None	Sun	Eye	Eye	Eye

CT = Commercial Treater; T/P = Treater/Planter on-farm

FT = Gustafson Farmer Applied Seed Treater (FAST); Shop-made = commercial shop-made treater; TST = Gustafson Total Slurry Treater;

CS 1700 = Gustafson CS 1700 commercial seed treater

[a] The mixer/loader task was performed with handlers wearing chemical resistant gloves (rubber latex),

[b]. The Study Report mentioned that each subject wore socks and leather boots with the exception of Replicate #14, who wore leather shoes.

[c] All handlers wore a ball cap with the exception of Replicate #12 who wore a visor, and Replicate #11 who did not wear a hat.

[d] Protective Eyeware included prescription glasses (Eye), safety glasses (Safety), and sunglasses (Sun).

4. Personal Protective Equipment:

Handlers wore the label required personal protective equipment (PPE) consisting of long sleeve shirt and pants, chemical resistant gloves, shoes and socks. One of the workers also elected to wear a dust mask at various times during the work period. Fourteen of the 16 workers wore a baseball cap. One worker wore a visor and the last worker did not wear a hat. A summary of the clothing and PPE worn by each worker is provided in Table 2.

5. Mixing/loading/application method:

The handlers conducted their work activities according to their normal practices. Research personnel observed worker activities and did not direct or influence workers in the handling of the test substance, set-up or calibration of treating equipment, treatment of seed, or planting of treated seed. With the exception of the Gustafson CS 1700, all of the seed treatment equipment used in the study delivered the seed treatment to a grain auger, where seed treatment and seed were mixed by the action of the auger. The Gustafson CS 1700 treater includes a mixing chamber where seed treatment and seed were mixed. The test substance, GAUCHO 480 SC, was used concurrently with RAXIL MD Extra to treat the seeds. The test substance was provided in plastic 32 oz bottles and RAXIL MD Extra (tank mix partner) was provided in 2.5 gallon plastic jugs. Mixing was accomplished by open pouring of the GAUCHO 480 SC into either a container of RAXIL MD Extra, a mixing container, or directly into the reservoir of the seed treating equipment. The treated seed was transferred to either a storage hopper or planter. Commercial handlers treated from 835 to 990 bushels of seed. On-farm treater/planters treated from 165 to 480 bushels of seed and planted 16 to 186 acres. Treater/planter normal work practices may include planting less seed than treated, leaving some seed in the seeding equipment or grain truck.

The activity of each worker was monitored and recorded. Activities that may have increased potential exposure to the test substance when not mixing or treating the seeds were recorded. These activities included, climbing into the truck bin with treated seed to rake seed into the auger, spreading seed in the seeder hopper during refills, checking placement of seed in the soil, adjusting seeding equipment, removing dirt built up on the planter, and when shaking rinsate in the test substance containers.

6. Application Rate:

Application rate(s): According to the Registrant, the equipment was calibrated for use of RAXIL at approximately 5 fl oz/100 lbs cereal seed. The observed mix ratio of approximately 21 fl oz test substance per 2.5 gallons of RAXIL MD yielded a treating rate equivalent to the rate of 0.32 fl oz GAUCHO 480 per 100 lbs seed (0.01 lb ai/100 lbs seed). The current imidacloprid label for a flowable product (Reg. 264-957) indicates a maximum application rate of 3.0 fl oz per hundredweight of seed (0.1 lb ai/100 lbs seed) can be used with a Total Slurry Treater (TST), Farmer Applied Seed Treater (FAST), Gustafson Air Pressure System (GAP) or other on-farm seed treating equipment when treating wheat, barley, oats, rye and triticale seed. The rate used in this study, 0.32 fl oz product/100 lbs seed, is specified on the label as for treatment of wireworms.

Application Regime: A single application was made.

Application Equipment: Several types of treating equipment were used in this study. They include the

Gustafson Farmer Applied Seed Treater (FAST), the Gustafson Total Slurry Treater (TST), the Gustafson CS 1700, and shop-made equipment.

Spray Volume: Not reported

Equipment Calibration Procedures: Calibration of the treating equipment was performed prior to treating the seeds; however, the procedures were not provided.

7. **Exposure monitoring methodology:**

Dermal: Dermal exposure was monitored using inner whole body dosimeters, which consisted of a one-piece, white, 100% cotton long-underwear union suit. At the end of each monitoring period, the inner suit was removed with the help of the study monitors and cut into the following sections:

1. Left/Right upper arms combined (elbow to shoulder seam)
2. Left/Right lower arms combined (elbow to cuff)
3. Left/Right upper legs combined (waist to knee)
4. Left/Right lower legs combined (knees to cuff)
5. Torso – front (above the waist)
6. Torso – back (above the waist)

Each cut section was then wrapped individually in aluminum foil, labelled, put in plastic bags and then placed in a freezer.

Face and Neck: Face/neck exposure was monitored using a 4 x 4 inch, 8 ply, 100% cotton gauze pad, moistened with 4 mL of 0.01% (v/v) Aerosol OT (AOT) solution. The pad was then wiped across the face, front and back of the neck of the worker by a field investigator wearing clean latex gloves. The pad was then placed on a piece of aluminium foil. The process was repeated with a second pad, combining both pads on the same foil. The foil was then folded, placed in a labelled plastic re-sealable bag and then placed in a freezer. Face/neck wipes were used when the worker stopped for lunch and at the end of the monitoring period. If a lunch-time face/neck wipe was conducted for a particular worker, the foil containing the lunch-time wipe was removed form the freezer, and the end-of-monitoring wipe was placed in the same foil, yielding one face/neck wipe sample for analysis per worker. Face/neck wipe samples were stored frozen until analysis.

Hand: Hand washes were performed to evaluate potential dermal exposure to the hands. Each hand wash was treated as a separate sample. Each handler placed both hands over a stainless steel bowl and washed them as a researcher poured 400 mL of an aqueous solution of 0.01% v/v Aerosol OT (AOT) over the hands. The handler vigorously rubbed his hands together in the wash solution for approximately 30 seconds. The worker then removed his hands from the solution and held them over the bowl while the field investigator poured a final 100 mL AOT rinse over the palm and back surfaces of the hand. The rinsate was then decanted into a labelled glass jar with Teflon lined lid, placed into a plastic re-sealable bag, and then into a field cooler. At the end of the monitoring period, aliquots of all hand wash samples were extracted using solid phase extraction (SPE) cartridges. During the monitoring period, hand washes were performed at any bathroom and lunch breaks and at the end of the

monitoring period. The number of hand washes per worker ranged from one to three.

Inhalation: Airborne concentrations of imidacloprid in the worker's breathing zone were monitored utilizing an OVS tube sample collector (connected by Tygon-type tubing) to a uniquely numbered personal air sampling pump. The pumps were operated at a flow rate of 2.0 L/min. The sample collector consisted of a glass fiber filter at the air inlet, followed by two sections of XAD-2 (270 and 140 mg separated by a polyurethane plug) housed in a 13 mm diameter glass tube. The OVS tube was held in a plastic tube holder and clipped to the worker's outer shirt collar with the intake facing downward. Airflow rates of the pumps were measured at the beginning and at the end of each exposure period using a calibrated Bios DryCal flow meter. Pumps were connected to the OVS tube sample when the airflow was measured at the beginning and end of the exposure period. The air sampling pumps operated for the total monitoring period.

After sampling, the OVS tube was disconnected from the tubing, capped at both ends, labelled, placed into a re-sealable plastic bag, and then into frozen storage. The pump on/off times and starting and ending flow rates were recorded.

All samples were stored in a freezer located in the research trailer during the field phase, and moved to a facility based freezer at conclusion of exposure monitoring. Freezer storage temperatures ranged from -11.1 to -31.3°C throughout the storage period. All of the field samples were shipped frozen via A.C.D.S. to the analytical laboratory. Upon arrival at the analytical facility, all of the samples were immediately transferred to frozen storage (<-15°C) until analysis. Maximum storage intervals for samples in this study were 109 days for inner dosimeter, 93 days for hand wash samples, 99 days for face/neck wipes, and 87 days for OVS tubes. All samples were analyzed within 9 days of extraction.

8. Analytical Methodology:

Extraction method(s):

Dosimeters – Dosimeters were extracted with methanol (MeOH). The extracts were amended with an imidacloprid-^{13}C-D_3 internal standard (IS). A small aliquot was eluted through a C18 solid phase extraction (SPE) cartridge into a culture tube. The solvent was removed on TurboVap. The sample was dissolved in MeOH and diluted with 0.1% aqueous formic acid for analysis by LC/MS-MS.

Face/Neck Wipes – Face/neck wipe samples were extracted with MeOH. The extracts were amended with an imidacloprid-^{13}C-D_3 IS. An aliquot was eluted through a C18 SPE cartridge into a culture tube. The extracts were diluted with 0.1% aqueous formic acid for analysis by LC/MS-MS.

Hand Wash – Hand wash samples were amended with an imidacloprid-^{13}C-D_3 IS. A small aliquot was loaded onto a C18 SPE cartridge and washed with water. The cartridge was frozen and shipped to the analytical laboratory. The SPE cartridge was eluted with MeOH into a culture tube. The solvent was removed on TurboVap. The sample was dissolved in MeOH and diluted with 0.1% aqueous formic acid for analysis by LC/MS-MS.

OVS-2 Tubes – OVS-2 tubes were separated into top and bottom sections and each section was placed in a 20 mL vial. The vial contents were extracted with MeOH and the extracts were

amended with an imidacloprid-^{13}C-D_3 IS. Aliquots of the extracts were diluted with 0.1% aqueous formic acid for analysis by LC/MS-MS.

Detection method(s): Samples were analyzed using high performance liquid chromatography with tandem mass spectrometers (LC/MS-MS). HPLC separation was performed with a Waters Xterra MS C18, 50 mm x 2.1 mm column, using 0.1% aqueous formic acid and MeOH as mobile phases on a ThermoFinnigan Surveyor HPLC. The HPLC was interfaced to a ThermoFinnigan Quantum Ultra tandem mass spectrometer for analyte detection.

Method validation: The method was validated prior to initiation of the study by fortifying the matrices with imidacloprid at three to four fortification levels. Recoveries averaged 107±15.9% (n=20) for dosimeters, 91.2±1.40% (n=12) for face/neck wipes, 102±5.56% (n=18) for hand washes, and 103±3.71% (n=12) for OVS-2 tubes.

These data support a method limit of quantitation (LOQ) of 1.0 µg imidacloprid in dosimeters, wipes, and hand washes and 0.025 µg imidacloprid in OVS-2 tubes. The limits of detection (LOD) for imidacloprid in dosimeters, wipes, hand washes and OVS-2 tubes were 0.04 µg/sample, 0.05 µg/sample, 0.15 µg/sample, and 0.004 µg/sample, respectively.

Instrument performance: The relative response of the LC/MS-MS to imidacloprid was linear over the range of 0.005 µg to 6,250 µg. The correlation coefficients of the linearity curves were all >0.99.

Quantification: Quantitation of imidacloprid residues in all samples was performed by selected reaction monitoring liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) analysis using a [^{13}C-D_3] internal standard. The response of the analyte and the corresponding internal standard was measured in samples and in standards, and a relative response was calculated. The relative responses of the analyte in the samples were then compared to the relative response of the analyte in standard solutions.

9. Quality Control:

Lab Recovery: According to the study protocol, at least one concurrent recovery sample and one field fortification sample at each fortification level was to be included with each sample set in order to validate recovery of the analyte from the treated samples. Concurrent recoveries were not provided with the report. However, this may be due to the fact that the field samples were injected with a [^{13}C-D_3] internal standard just prior to analysis. It is possible that the concurrent recoveries could be the method validation recovery samples which were discussed in Section 8 of this report. The report did not state that the method was validated prior to sample analysis.

Field blanks: Triplicate control samples for each matrix were prepared in the field on the four days that field fortification samples were prepared. Weathered samples were placed in areas least likely to experience contamination from mix, load, treat or planting activities. The OVS tubes and representative inner dosimeter sections were exposed to environmental conditions and for the approximate duration of the longest replicate work period on that day. Face/neck wipe samples were placed in frozen storage

immediately and hand wash samples were prepared and field stored for a short period of time to mimic handling of the worker collected samples.

At the end of the designated period, all control matrices were handled in the same manner as field samples and placed in frozen storage prior to shipping to the analytical laboratory.

There were no residues of imidacloprid detected above the LOQ (1.0 µg/sample for dosimeters, hand wash and wipes and 0.025 µg/sample for OVS tubes) in any of the control samples. Imidacloprid residues were detected in three of the control inner dosimeters at levels up to 0.17 µg/sample, seven face/neck wipe samples at levels up to 0.42 µg/sample, one hand wash sample at 0.27 µg/sample and one OVS tube at the LOD (0.004 µg/sample).

The registrant adjusted the field fortification recoveries for average control sample contribution. The reviewer did not correct the field or the field fortification samples for observed residues in the control samples.

Field recovery: Field fortification samples were prepared in the field during four of the 16 field trials. Control samples for each matrix were fortified at three levels in triplicate. The inner dosimeters and hand wash samples were prepared at 5.0, 100, and 5,000 µg/sample. Face/neck wipes were prepared at 5.0, 100, and 2,500 µg/sample. The OVS tubes were prepared at 0.05, 1.0, and 50 µg/sample.

The fortified dosimeter and OVS tube samples were weathered by placing them in areas least likely to experience contamination from mix, load, treat or planting activities but exposed to the environment for the approximate duration of the longest replicate work period on that day. Fortified face/neck wipe samples were placed in frozen storage immediately and hand wash samples were prepared and field stored for a short period of time to mimic handling of the worker collected samples. After fortification and weathering, the samples were handled in the same manner as the field samples.

The Study Author calculated recoveries using background corrected residues but did not follow the same procedure for the field samples. Versar did not adjust the field fortification recoveries for background levels. The calculated recoveries are shown in Table 3.

The fortification levels were not representative of the residue levels determined in the face/neck wipe field samples. For the face/neck wipes, most of the samples had residues below the lowest fortification level. Average recoveries were all within the acceptable range of 70 to 120%.

Table 3. Summary of Imidacloprid Field Fortification Recoveries						
Matrix	Spike Level (µg)	Sample Size (n)	Minimum % Recovery	Maximum % Recovery	Average % Recovery	Std. Dev.
Inner Dosimeters	5	12	66.6	87.8	78.3	5.90
	100	12	69.9	83.9	77.3	4.43
	5000	12	74.8	86.1	82.1	3.96
Hand Washes	5	12	94.4	117	103	7.52
	100	12	91.8	111	102	6.83
	5000	12	92.6	128	105	12.9
Face/Neck Wipes	5	12	71.0	97.8	84.9	8.63
	100	12	68.0	86.3	79.7	6.31
	2500	12	80.1	87.2	83.1	2.46
OVS Tubes	0.05	12	92.0	110	102	5.69
	1	12	82.7	99.1	92.2	5.17
	50	12	90.6	104	97.4	5.01

Notes: Field fortification recoveries were not adjusted for background contribution.

Formulation: GAUCHO 480 SC (also called GAUCHO 480 F) is a solution concentrate or flowable formulation containing 41.67% of the active ingredient (ai) imidacloprid.

Tank mix: Analysis of the tank mix was not conducted.

Travel Recovery: Travel spikes were not prepared in this study.

Storage Stability: Maximum storage intervals for samples in this study were 109 days for inner dosimeter, 93 days for hand wash samples, 99 days for face/neck wipes, and 87 days for OVS tubes. All of the samples were analyzed within 9 days of extraction. According to the registrant, field fortification recoveries which were conducted concurrently with field sample sets ensured the integrity of the samples and extracts from initial generation through field storage, transport, storage at the analytical facility, and through the period of time between sample extraction and analysis. No additional storage stability data was thought to be required.

Corrections to the field samples were made using the field fortification recoveries, which included any losses during storage.

10. Relevancy of Study to Proposed Use:

The study design and the proposed uses for this chemical are similar.

II. RESULTS AND CALCULATIONS:

The Registrant provided dermal and inhalation exposure values for each replicate expressed as µg/sample and µg /kg ai handled. Versar corrected all dermal and inhalation raw residue values using the mean field fortification recovery of the closest field fortification level, when the recovery was less than 100%. Versar did not correct the field residues for field fortification recoveries greater than 100%. Versar did not correct field residues detected below the LOQ for each matrix. The Registrant adjusted the measured residues in each matrix based on the recovery of field fortified samples analyzed concurrently with each sample set. The Registrant also corrected residues to 100%.

The limit of quantitation (LOQ) for the analytical method was 1 µg/sample for all dermal samples and 0.025 µg/sample for the OVS tubes. The limit of detection was 0.04, 0.15, 0.05, and 0.004 µg/sample for the inner dosimeters, hand washes, face/neck wipes, and OVS tubes, respectively. For residues reported as <LOQ or <LOD, a value of ½ the LOQ or ½ the LOD was used for calculation purposes. The registrant used the LOQ or LOD value for calculation purposes.

Versar estimated dermal exposure and inhalation exposure values as µg/lb ai handled. The exposure values calculated by Versar are shown in Tables 4 through 7.

Dermal Results

Residues were above the detection limit in the majority of the samples. Dermal exposure was estimated by measuring inner WBD, face/neck wipe and hand wash residues.

Total dermal exposures for commercial seed treaters and on-farm treater/planters normalized by pound ai handled, are shown in Tables 4 and 5. Total dermal exposure was determined by summing the estimated inner dosimeter exposure, hand exposure (hand wash residues after exposure), and face/neck exposure (face/neck wipes). Total dermal exposure ranged from 26.4 to 137 µg/lb ai, with an average of 72.0 ± 49.0 µg/lb ai for commercial treaters and from 6.61 to 231 µg/lb ai with an average of 65.4 ± 68.1 µg/lb ai for on-farm treater/planters.

As shown in Tables 4 and 5, the majority of the contribution by body part was from the hands for the commercial treater replicates (average of 72.7%) and for the treater/planter replicates (average of 58.4%).

Inhalation Results

Tables 6 and 7 provide a summary of the Versar-calculated inhalation exposures for the on-farm treater/planters and commercial treaters. Imidacloprid residues were not detected in the back section of the OVS tubes. The personal monitoring pumps were set at an airflow of approximately 2.0 L/min. Versar used the NAFTA recommended inhalation rates of 0.0167 m^3/min (light activities) for the mixer/loader/applicator workers when calculating the inhalation exposure. Total inhalation exposure ranged from 0.07 to 31.3 µg/lb ai with an average of 3.52 ± 8.78 µg/lb ai for on-farm treater/planters and from 0.107 to 1.55 µg/lb ai with an average of 0.548 ± 0.673 µg/lb ai for commercial treaters.

Registrant Results

Versar and the Registrant used the same basic method to calculate total dermal exposure and inhalation exposure. Differences in both the dermal and inhalation exposure estimates are partially a result of field fortification correction methods used. The field fortification recoveries applied by Versar were not

corrected for background residues, whereas the field fortification recoveries applied by the Registrant were corrected for background residues. Also, the Registrant corrected residues less than the LOQ, whereas Versar did not and the Registrant corrected residues for field fortification recoveries >100% using field fortification samples from the same sample set as when the field sample was analyzed, while Versar applied the average recoveries (<100%) from the fortification level most representative of actual field residue level to correct the field residues.

III DISCUSSION:

A. LIMITATIONS OF THE STUDY:

Issues of concern when reviewing this study are:

- **Application Rate**
  The handlers treated the cereal seed with the label specified maximum rate for wireworm treatment (0.32 fl oz product/100 lbs seed). The label for GAUCHO 480 Flowable (EPA Reg. No. 264-957) obtained from EPA's PPLS specifies a rate that is 10 times greater for wheat seed treatment against other insects (3.0 fl oz product/100 lbs seed).

- **Field Fortification**
  The fortification levels were not representative of the residue levels determined in the field samples for face/neck wipes. Face/neck wipe sample residues were primarily below the lowest fortification level.

  Also, field fortification samples were prepared at only 4 of the 16 trials.

Table 4. Imidacloprid: Summary of Total Dermal Exposure (µg/lb ai) for Commercial Treaters[1,2]

Replicate	Total Inner Dosimeter Residue (µg)	Face/Neck Wipes (µg)	Hand wash Residues[4] (µg)	Total Dermal Residue (µg)	Amount Handled (lb ai)	Total Dermal Exposure[5] (µg /lb ai handled)
1	284	3.13	548	835	6.1	137
2	65.0	0.500[3]	104	170	6.4	26.4
12	62.0	1.59	161	225	5.3	42.7
14	28.3	3.74	380	412	5.0	82.2
Overall Average	110	2.24	298	410	5.7	72.0
Overall Standard Deviation	117	1.47	205	301	0.67	49.0
Overall Geomean	75.4	1.75	243	338	5.7	59.7
CV (%)	107	65.7	68.5	73.4	11.8	68.1
Min	28.3	0.500	104	170	5.0	26.4
Max	284	3.74	548	835	6.4	137

Notes:

1. Dermal exposure represents a handler wearing chemical resistant gloves and a single layer of clothing (long sleeve shirt and long pants).
2. Field residues were corrected when the average recovery from the fortification level closest to the residue level was <100% (see Table 3).
3. Value based on residues that were <LOQ; ½ LOQ was used in calculations when residues were reported as <LOQ.
4. Hand Exposure (µg/lb ai) = ∑hand wash residue during and after exposure / lb ai handled
   Chemical resistant gloves were worn during the study
5. Total Dermal Exposure (µg/lb ai) = sum of arm, leg, torso, hand, face and neck exposure.

Table 5. Imidacloprid: Summary of Total Dermal Exposure (µg/lb ai) for On-farm Treater/Planters[1,2]

Replicate	Total Inner Dosimeter Residue (µg)	Face/Neck Wipes (µg)	Hand wash Residues[5] (µg)	Total Dermal Residue (µg)	Amount Handled (lb ai)	Total Dermal Exposure[6] (µg /lb ai handled)
3	24.5	2.34	186	213	1.3	162
4	17.4	1.93	36.9	56.3	2.0	28.1
5[7]	5.2	0.500[3]	2.79	8.50	1.3	6.61
6	24.2	1.98	67.8	94.0	1.3	73.2
7	11.5	1.34	141	154	2.8	55.7
8	294	6.14	430	730	3.2	231
9	140	9.43	40.0	189	2.0	96.0
10	7.44	0.500[3]	32.7	40.6	1.3	30.9
11	5.14	0.500[3]	14.8	20.4	2.0	10.4
13	43.7	0.500[3]	12.0	56.2	1.6	34.5
15	4.35	0.025[4]	8.33	12.7	1.3	9.66
16	100	2.33	23.2	125	2.6	47.7
Overall Average	56.4	2.29	82.9	142	1.89	65.4
Overall Standard Deviation	86.0	2.78	123	198	0.657	68.1
Overall Geomean	22.7	1.08	35.1	70.5	1.79	39.3
CV (%)	152	121	148	140	34.8	104
Min	4.35	0.025	2.79	8.50	1.28	6.61
Max	294	9.43	430	730	3.16	231

Notes:

1. Dermal exposure represents a handler wearing chemical resistant gloves and a single layer of clothing (long sleeve shirt and long pants).
2. Field residues were corrected when the average recovery from the fortification level closest to the residue level was <100% (see Table 3).
3. Value based on residues that were <LOQ; ½ LOQ was used in calculations when residues were reported as <LOQ.
4. Value based on residue that were <LOD; ½ LOD was used in calculations when residues were reported as <LOD.
5. Hand Exposure (µg/lb ai) = ∑hand wash residue during and after exposure / lb ai handled
   Chemical resistant gloves were worn during the study
6. Total Dermal Exposure (µg/lb ai) = sum of arm, leg, torso, hand, face and neck exposure.
7. Handler only worked a half day due to inclement weather.

Table 6. Imidacloprid: Inhalation Exposure for Commercial Treaters

Rep	Corrected Residues (µg)	Duration (min)	Flow Rate (L/min)	Volume (L)	Volume (m^3)	Concentration (µg/m^3)	lb ai handled	Vent. Rate (m^3/min)	Inhalation exposure (µg /lb ai handled)
1	1.12	390	2.0	772	0.772	1.45	6.1	0.0167	1.55
2	0.159	472	2.0	959	0.959	0.166	6.4	0.0167	0.204
12	0.066	256	2.0	500	0.500	0.132	5.3	0.0167	0.107
14	0.198	635	2.0	1260	1.26	0.157	5.0	0.0167	0.332
Overall Average									0.548
Overall Standard Deviation									0.673
Overall Geomean									0.325
CV (%)									123
Min									0.107
Max									1.55

Notes:

1. Concentration (µg/m^3) = Total corrected residues (µg) / Volume (L) * 1000
2. Inhalation Exposure (µg) = concentration (µg/m^3) * NAFTA ventilation rate for light activities (1.0 m^3/hr) * Duration (min) * 1 hr /60 min

Table 7. Imidacloprid: Inhalation Exposure for On-farm Treater/Planters

Rep	Corrected Residues (µg)	Duration (min)	Flow Rate (L/min)	Volume (L)	Volume (m^3)	Concentration (µg/m^3)	lb ai handled	Vent. Rate (m^3/min)	Inhalation exposure (µg /lb ai handled)
3	0.182	574	2.0	1127	1.13	0.162	1.3	0.0167	1.18
4	0.594	591	2.0	1185	1.18	0.501	2.0	0.0167	2.47
5	0.095	227	2.0	450	0.450	0.211	1.3	0.0167	0.623
6	0.297	526	2.0	1075	1.08	0.276	1.3	0.0167	1.89
7	0.058	503	2.0	995	0.995	0.058	2.8	0.0167	0.176
8	0.695	672	2.0	1376	1.38	0.505	3.2	0.0167	1.79
9	7.15	672	1.9	1300	1.30	5.50	2.0	0.0167	31.3
10	0.047	598	2.0	1167	1.17	0.040	1.3	0.0167	0.302
11	0.076	488	2.0	976	0.976	0.078	2.0	0.0167	0.324
13	0.163	390	2.0	797	0.797	0.204	1.6	0.0167	0.816
15	0.011	605	1.9	1174	1.17	0.009	1.3	0.0167	0.070
16	0.394	572	2.0	1125	1.13	0.350	2.6	0.0167	1.27
Overall Average									3.52
Overall Standard Deviation									8.78
Overall Geomean									0.887
CV (%)									250
Min									0.070
Max									31.3

Notes:

1. Concentration (µg/m^3) = Total corrected residues (µg) / Volume (L) * 1000
2. Inhalation Exposure (µg) = concentration (µg/m^3) * NAFTA ventilation rate for light activities (1.0 m^3/hr) * Duration (min) * 1 hr /60 min

Name:
Evaluator
Occupational Exposure Assessment Section

Date

Name:
Peer Reviewer
Occupational Exposure Assessment Section

Date

Name:
Head,
Occupational Exposure Assessment Section

Date

Appendix A

COMPLIANCE CHECKLIST
GUIDELINE 875.1100
DERMAL EXPOSURE- OUTDOOR HANDLER

1. *Investigators should submit protocols for review purposes prior to the inception of the study.*
It is not certain if this criterion was met. The signed study protocol is included in the Study Report, however, it is uncertain if this protocol was submitted to EPA prior to inception of the study.

2. *Expected deviations from GLPs should be presented concurrently with any protocol deviations and their potential study impacts.*
This criterion was met. Protocol deviations were reported.

3. *The test substance should be a typical end use product of the active ingredient.*
This criterion was met.

4. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate may be more appropriate in certain cases.*
This criterion was not met. The Registrant stated that the application rate used in the study (0.32 fl oz product /100 seeds) was the maximum application rate. The label for GAUCHO 480 Flowable (EPA Reg. No. 264-957) obtained from EPA's PPLS stated that the maximum application rate for wheat seed is 3.0 fl oz product per 100 seeds.

5. *Selected sites and seasonal timing of monitoring should be appropriate to the activity.*
This criterion was met.

6. *A sufficient number of replicates should be generated to address the exposure issues associated with the population of interest. For outdoor exposure monitoring, each study should include a minimum of 15 individuals (replicates) per activity.*
This criterion was met. There were 16 seed treater replicates, however, there were two types of seed treaters (commercial treaters and on-farm treater/planters). There were less than 15 replicates for each type of seed treater.

7. *The quantity of active ingredient handled and the duration of the monitoring period should be reported for each replicate.*
This criterion was met.

8. *Test subjects should be regular workers, volunteers trained in the work activities required, or typical homeowners.*
This criterion was met.

9. *Any protective clothing worn by the test subjects should be identified and should be consistent with the product label.*
This criterion was met.

10. *The monitored activity should be representative of a typical working day for the specific task in*

order to capture all related exposure activities.
This criterion was met. Handlers were monitored during their normal workday activity. Commercial seed treaters worked 4.3 to 10.6 hours (average of 7.3 hours) and on-farm treater/planters worked 3.8 to 11.2 hours (average of 9 hours).

11. *Dermal exposure pads used for estimating dermal exposure to sprays should be constructed from paper-making pulp or similar material (i.e., alpha-cellulose), approximately 1 mm thick, that will absorb a considerable amount of spray without disintegrating. The alpha-cellulose material should not typically require preextraction to remove substances that interfere with residue analysis. This should be determined prior to using the pads in exposure tests.*
This criterion is not applicable. Cotton whole body dosimetry was used in this study.

12. *Dermal exposure pads used for estimating dermal exposure to dust formulations, dried residues, and to dust from granular formulation should be constructed from layers of surgical gauze. The pad should be bound so that an area of gauze at least 2.5 inch square is left exposed. The gauze must be checked for material that would interfere with analysis and be preextracted if necessary.*
This criterion is not applicable, as a liquid formulation was used and cotton matrix dosimetry was used.

13. *A complete set of pads for each exposure period should consist of 10 to 12 pads. If the determination of actual penetration of work clothing is desired in the field study, additional pads can be attached under the handler's outer garments. Pads should be attached under both upper and lower outer garments, particularly in regions expected to receive maximum exposure. Pads under clothing should be near, but not covered by, pads on the outside of the clothing.*
This criterion is not applicable, because body dosimeters were used in this study.

14. *If exposed pads are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.*
This criterion is not applicable since pads were not used.

15. *Hand rinses should be performed during preliminary studies to ensure that interferences are not present. Plastic bags designed to contain 0.5 gal and strong enough to withstand vigorous shaking (i.e., at least 1 mil inch thickness) should be used. During preliminary studies, plastic bags must be shaken with the solvent to be used in the study to ensure that material which may interfere with analysis is not present.*
This criterion is not applicable, as hand rinses were collected in glass bottles and field fortifications were analyzed which would to monitor for interfering substances in the containers.

16. *The analytical procedure must be capable of quantitative detection of residues on exposure pads at a level of 1 ug/cm^2 (or less, if the dermal toxicity of the material under study warrants greater sensitivity).*
It is not certain if this criterion was met because exposure pads were not used in this study.

17. *The extraction efficiency of laboratory fortified controls is considered acceptable if the lower limit of the 95% confidence interval is greater than 75%, unless otherwise specified by the Agency. At a minimum, seven determinations should be made at each fortification level to calculate the mean and standard deviation for recovery. Total recovery from field-fortified samples must be greater than 50% for the study.*

Laboratory fortification sample results were not reported. An internal standard was used.

18. *If the stability of the material of interest is unknown, or if the material is subject to degradation, the investigator must undertake and document a study to ascertain loss of residues while the pads are worn. It is recommended that collection devices be fortified with the same levels expected to occur during the field studies. The dosimeters should be exposed to similar weather conditions and for the same time period as those expected during field studies.*
This criterion was partially met. Field fortification was conducted, however, the fortification levels were not representative of the residue levels determined in the face/neck field samples Face/neck field sample residues were predominantly below the lowest fortification level.

19. *Data should be corrected if any appropriate field fortified, laboratory fortified or storage stability recovery is less than 90 percent.*
This criterion was met.

20. *Field data should be documented, including chemical information, area description, weather conditions, application data, equipment information, information on work activity monitored, sample numbers, exposure time, and any other observations.*
This criterion was met.

21. *A sample history sheet must be prepared by the laboratory upon receipt of samples.*
This criterion was met.

COMPLIANCE CHECKLIST
GUIDELINE 875.1300
INHALATION EXPOSURE- OUTDOOR HANDLER

1. *When both dermal and inhalation monitoring are required, field studies designed to measure exposure by both routes on the same subjects may be used.*
This criterion was met.

2. *The analytical procedure must be capable of measuring exposure to 1 ug/hr (or less, if the toxicity of the material under study warrants greater sensitivity).*
This criterion was met.

3. *A trapping efficiency test for the monitoring media chosen must be documented.*
This criterion was met. A method validation study was performed.

4. *Air samples should also be tested for breakthrough to ensure that collected material is not lost from the medium during sampling. It is recommended that at least one test be carried out where the initial trap contains 10X the highest amount of residue expected in the field.*
This criterion was met. Both the front and back sections of the tubing were analyzed for breakthrough.

5. *If trapping media or extracts from field samples are to be stored after exposure, a stability test of the compound of interest must be documented. Media must be stored under the same conditions as field samples. Storage stability samples should be extracted and analyzed immediately before and at appropriate periods during storage. The time periods for storage should be chosen so that the longest corresponds to the longest projected storage period for field samples.*
This criterion was met. Field fortification samples were used to support storage stability.

6. *A personal monitoring pump capable of producing an airflow of at least 2 L/min. should be used and its batteries should be capable of sustaining maximum airflow for at least 4 hours without recharging. Airflow should be measured at the beginning and end of the exposure period.*
This criterion was met.

7. *Appropriate air sampling media should be selected. The medium should entrap a high percentage of the chemical passing through it, and it should allow the elution of a high percentage of the entrapped chemical for analysis.*
This criterion was met.

8. *If exposed media are to be stored prior to extraction, storage envelopes made from heavy filter paper may be used. The envelope must be checked for material that will interfere with analysis. Unwaxed sandwich bags should be used to contain the filter paper envelopes to help protect against contamination.*
This criterion was met. Air tube samples were placed in re-sealable plastic bags and were not exposed to the air prior to sampling.

9. *Personal monitors should be arranged with the intake tube positioned downward, as near as possible to the nose level of the subject.*
This criterion was met.

10. *Field calibration of personal monitors should be performed at the beginning and end of the exposure period.*
This criterion was mostly met. A deviation from the protocol mentioned that not all of the pumps were calibrated prior to use. Verified end flow rates were used in flow calculations.

11. *Field fortification samples and blanks should be analyzed for correction of residue losses occurring during the exposure period. Fortified samples and blanks should be fortified at the expected residue level of the actual field samples. Fortified blanks should be exposed to the same weather conditions.*
This criterion was met.

12. *Respirator pads should be removed using clean tweezers and placed in protective white crepe filter paper envelopes inside sandwich bags. The pads should be stored in a chest containing ice until they are returned to the laboratory, where they should be stored in a freezer prior to extraction.*
This criterion was not met. The air sampling tubes were placed in a plastic bag.

13. *Analysis methods should be documented and appropriate.*
This criterion was met.

14. *A sample history sheet must be prepared by the laboratory upon receipt of samples.*
This criterion was met.

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R190270

Chemical Name: Imidacloprid

PC Code: 129099
HED File Code: 12000 Exposure Reviews
Memo Date: 2/22/2011
File ID: 00000000
Accession #: 000-00-0137

HED Records Reference Center
2/28/2011